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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,919	03/22/2001	Bettina Mockel	P 277862 990217 BT	1875

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EXAMINER
SWITZER, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/813,919	MOCKEL ET AL.	
	Examiner	Art Unit	
	Juliet C. Einsmann	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 December 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-17 and 19-25* is/are pending in the application.

4a) Of the above claim(s) *8-14,16 and 17* is/are withdrawn from consideration.

5)☒ Claim(s) *23 and 24* is/are allowed.

6)☒ Claim(s) *6,7,15,22 and 25* is/are rejected.

7)☒ Claim(s) *6,7 and 19-21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is written in response to applicant's correspondence submitted 12/24/02. Claims 6, 7, 15, and 19-21 have been amended, claims 1-5 and 18 have been canceled, and claims 22-25 have been added. Claims 6-17 and 19-25 are pending. Claims 8-14, 16, and 17 are withdrawn from prosecution because they are drawn to a non-elected invention. Claims 6-7, 15, and 19-25 are examined herein. The response also included a certified translation of the priority document and a declaration of biological deposit. Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is FINAL.**

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 601.01(a).

The declaration filed 6/20/01 does not contain the serial number of the application filed 3/22/01. Instead, the declaration merely recites "was filed on March 22, 2001 as U.S. Application No. 09/..."

A new declaration is required.

Specification

3. The abstract of the disclosure is objected to because it does not accurately reflect the currently claimed invention. The abstract is essentially a recitation of cancelled claim 1 and should be corrected to reflect the instantly claimed invention. Correction is required. See MPEP § 608.01(b).

Election/Restrictions

4. This application contains claims 8-14, 16, and 17 drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Objections

5. Claim 6 is objected to because it recites a "Sector" instead of a "Vector." Correction is required. Claim 7 is objected to because it depends from claim 6.

6. Claim 19 is objected to because the word "activity" appears to have been left off of the end of the claim. Claims 20 and 21 are objected to because they depend from objected to claim 19.

Claim Rejections - 35 USC § 112

7. Claims 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection applies to claims 6 and 7 when they are interpreted so as to require plasmid pXT-dapCexp. In this case, it is apparent that the DNA insert of the plasmid deposited with DSM is required to practice the claimed invention. As such, it must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise known and readily available to the public. If it is not so obtainable or available, the requirements of 35 USC 112, first paragraph may be satisfied by an enabling deposit of the plasmid.

It is noted that Applicants have deposited the organism but there is not indication in the specification as to the public availability of the plasmid (see specification pages 26), thus it is considered insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met. If a deposit has been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released upon issuance of a patent would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

(a) during pendancy of the application, accession to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Amendment of the specification to recite the date of the deposit and the address of the depository is also required to satisfy the deposit requirement.

New Grounds of Rejection

8. Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen , 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

In the instantly rejected claims, the new limitation of "wherein said isolated DNA is isolated from a coryneform bacterium" as it is meant to modify either the DNA encoding SEQ ID NO: 4 or the portion of SEQ ID NO: 3 in claim 22 appears to represent new matter. The response filed 12/24/02 cited support for claim 22 in cancelled claim 18. However, cancelled claim 18 does not support instant claim 22. The specification discusses SEQ ID NO: 3 and SEQ ID NO: 4 at page 11 where the specification teaches that replacing the amino acid L-proline in position 209 of the enzyme (SEQ ID NO: 2) with L-leucine (the resulting polypeptide being SEQ ID NO: 4) enhancement occurs and the coryneform bacteria bearing the corresponding amino

acid replacement produce L-lysine in an improved manner. The specification goes on to discuss methodologies for site directed methodologies. The specification does not discuss or suggest that instant SEQ ID NO: 3 or SEQ ID NO: 4 were isolated from a coryneform bacterium. Turning to original claim 18, this claim states that the claimed DNA "originates" from coryneform bacterium, but never states that it was isolated from coryneform bacterium. As noted previously, however, it is not clear what it means for a nucleic acid to have originated from coryneform bacteria. Since no basis has been identified, the claims are rejected as incorporating new matter.

Claim Rejections - 35 USC § 103

9. Claims 15 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsumata *et al.* in view of Pompejus *et al.* (US 2003/0049804 A1).

Katsumata et al. teach a plasmid that comprises the dapC gene of Corynebacterium glutamicum (Col. 4, lines 13-16), and further teach Corynebacterium glutamicum comprising this plasmid (Col. 9). When the plasmid is expressed in the bacteria, RNA is produced. The segment of the C. glutamicum genome that is used in making the plasmid contains both the dapA and the dapC genes from C. glutamicum. Katsumata et al. teach that this plasmid comprises a polynucleotide encoding the same enzyme from the same species of bacteria as the instantly disclosed polynucleotide. Thus, it the dapC gene cloned into corynebacteria by Katsumata et al. appears to be identical to instant SEQ ID NO: 1. Applicant is reminded that MPEP 2112.01 teaches "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a

prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.'"

Katsumata do not teach isolated polynucleotides which consist of portions from within SEQ ID NO: 1 or which consist of SEQ ID NO: 1 in its entirety that are used as hybridization probes or as primers.

Pompejus *et al.* teach nucleic acids encoding metabolic enzymes from Corynebacterium glutamicum, and teach fragments of these nucleic acids for use as primers or probes for the detection of the sequences (see at least paragraphs 12, 62, and 70). Pompejus *et al.* specifically exemplify methods in which target nucleic acids are sequenced (paragraph 155) and teach that these sequenced nucleic acids can be used for the production of primers and probes for detection of the sequences themselves or related sequences.

Thus, in light of the teachings of Katsumata *et al.* in view of Pompejus *et al.* it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have sequenced the dapC gene provided by Katsumata *et al.* and selected primers and probes from within this sequence using the methodologies taught by Pompejus *et al.* The ordinary practitioner would have been motivated to undertake these steps for the selection of primers and probes within the C. glutamicum in order to practice the methodologies discussed by Pompejus *et al.*, who teach that the primers and probes to C. glutamicum sequences can be used in the identification of C. glutamicum and related organisms, identification and localization of C. glutamicum sequences of interest, to clone homologues of the genes of interest, to detect

transcripts or genomic sequences encoding the same or homologous proteins, for identifying cells which misexpress an MP protein, such as by measuring a level of an MP-encoding nucleic acid in a sample of cells from a subject e.g., detecting MP mRNA levels or determining whether a genomic MP gene has been mutated or deleted (¶ 70 and 130). Thus, in light of the teachings of Katsumata *et al.* in view of Pompejus *et al.* the instantly claimed invention is free of the prior art.

Response to Remarks

The rejections under 112 2nd are withdrawn in view of the amended claims.

The rejections under 102 in view of Katsumata *et al.* and Mahairas *et al.* are overcome in view of applicant's amendments to the claims. The rejections under 102 in view of Pompejus *et al.* are overcome in view of both the amendments to the claims and in view of the translation of the foreign priority document which provides enabling disclosure of instant SEQ ID NO: 1 and SEQ ID NO: 2.

Claims 6-7 remain rejected under 112 1st paragraph because the deposit rules have not been met. Applicant's declaration of biological deposit is not sufficient to overcome the rejection because it does not clearly set forth the date the deposit was made. The declaration indicates two different dates as dates of deposit (see ¶ number 3 of the declaration). Further, the specification has not been amended to recite the date of the deposit and the address of the depository, which amendment is also required to satisfy the deposit requirement.

New grounds of rejection are set forth to address the amended claims and the newly added claims.

Conclusion

10. Claims 23 and 24 are allowed. Claims 6-7 are free of the prior art and will be allowable once the deposit rules are satisfied. Claim 19 is objected to, but if the objection were overcome, claims 19, 20, and 21 would be allowable, as they are free of the prior art.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet Einsmann Switzer whose telephone number is 703 306 5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703 308 1152. The fax phone numbers for the

organization where this application or proceeding is assigned are 703 305 3592 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0196.

Juliet Einsmann Switzer
Art Unit 1634

April 9, 2003

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
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